K041399

1 of 3

JUL 28 2004

smiths

Smiths Medical ASD, Inc.
Anesthesia and Safety Devices Division
10 Bowman Drive
Keene NH 03431-0724 USA
Tel: +1 603 352 3812
Fax: +1 603 352 3703
www.smiths-medical.com

J: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY:

COMPANY INFORMATION:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene, NH 03431
(603) 352-3812
Contact: Brian D. Farias
Regulatory Affairs Manager

PREPARATION DATE OF SUMMARY:

May 25, 2004 (Revised July 22, 2004)

TRADE NAME:

Hypodermic Needle-Pro® EDGE™ Needle Protection Device.

COMMON NAME:

Hypodermic Needle with integral needle protection

PRODUCT CLASS/CLASSIFICATION:

Class II, 80 FMI, 21 CFR 880.5570 (Hypodermic Single Lumen Needles)

PREDICATE DEVICE(S):

K923127 Needle-Pro™ Cartridge and K951254 Becton Dickinson SafetyGlide™ Needles

DESCRIPTION:

This device is intended for injection or aspiration of fluids utilizing a standard Luer lock or Luer slip syringe. The needle protection device covers the needle after use to help prevent needle sticks. The device features a "one-piece" design of needle hub and protective sheath with a living hinge. The needle cannula is permanently affixed into the hub. The sheath has an "arrow" indicating the bevel orientation, i.e. when the sheath is oriented to the right, the bevel is in the "up position". After the procedure is completed, the needle is pressed into the sheath using a one-handed technique. As the needle enters the protective sheath, the needle is engaged under the hook and contained within the sheath. The device is then immediately discarded into a sharps container.

INDICATIONS FOR USE:

This device is intended for injection or aspiration of fluids utilizing a Luer Lock or Luer slip syringe. The needle protection device covers the needle after use to help prevent needle sticks.

TECHNICAL CHARACTERISTICS:

The proposed and predicate devices are made of similar materials and employ the same hinged style protective sheath that is manually activated after use.

NON-CLINICAL DATA:

Bench testing was conducted comparing the proposed and predicate devices; none of the data raises any new issues with regards to safety or efficacy.

Bench testing was performed on the basis of the following guidance documents and conformance to the following standards was demonstrated except for any inapplicable requirements or deviations identified for each standard in the submission.

> Guidance on the Content of Premarket Notification [510(k)] submissions for hypodermic single lumen needles, April 1993
>
> Supplementary Guidance on Premarket Notifications for Medical Devices with Sharps Injury Prevention Features; Guidance for Industry and FDA, December 31, 2002.
>
> ISO 594-1:1986(E), International Standard, *Conical fittings with a 6% taper for syringes, needles and certain other medical equipment-Part 1: General requirements*

K041399

3 of 3

ISO 594-2:1998(E), International Standard, *Conical fittings with a 6% taper for syringes, needles and certain other medical equipment-Part 2: Lock Fittings*

ISO 7864:1993(E), International Standard, *Sterile hypodermic needles for single use*)

CLINICAL DATA:

A simulated Clinical was conducted on the proposed device with Smiths Medical's predicate device as the control. The proposed device was well received and the study did not raise any new issues with regards to safety or efficacy.

CONCLUSION:

The comparison to the predicate devices demonstrates that the proposed device is safe and effective and is substantially equivalent to the predicate device.

Very truly yours,

SMITHS MEDICAL ASD, INC.

Brian D. Farias
Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 2004

Mr. Brian D. Farias
Regulatory Affairs Manager
Smiths Medical ASD, Incorporated
10 Bowman Drive
Keene, New Hampshire 03431-0724

Re: K041399
Trade/Device Name: Hypodermic Needle-Pro® EDGE™ Needle Protection Device
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: May 25, 2004
Received: May 26, 2004

Dear Mr. Farias:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

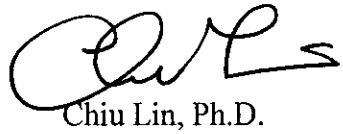
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K041399

B: INDICATIONS FOR USE OF DEVICE

Indications for Use

510(k) Number (if known): K041399

Device Name: Hypodermic Needle-Pro® EDGE™ Needle Protection Device

Indications for Use:

This device is intended for injection or aspiration of fluids utilizing a Luer Lock or Luer slip syringe. The needle protection device covers the needle after use to help prevent needle sticks.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anne Marie for ADW 7/27/04

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041399